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10/765,267	01/27/2004	Darryl J.C. Pappin	BP0207-US 3	9577

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APPLIED BIOSYSTEMS  
500 OLD CONNECTICUT PATH  
FRAMINGHAM, MA 01701

EXAMINER
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GRAZIER, NYEEMAH

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/765,267

Applicant(s)

PAPPIN ET AL.

Examiner

Nyeemah Grazier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) 54-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 23, 28, 36, 41-53 is/are rejected.
- 7) ☒ Claim(s) 16-22, 24-27, 29-35, 37-40 and 42-53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/30/04, 8/9/04
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**I. ACTION SUMMARY**

Claims 1-53 are currently pending in the instant application and are subject to the required restrictions and elections as described below. Claims 54-70 are withdrawn under 37 CFR 1.142(b) as non-elected subject matter.

Claims 1-14, 41-53 are rejected for obviousness double patenting. Claims 1, 15, 23, 28, 36, 41 and 49 are rejected under 35 U.S.C. 112, second paragraph.

**II. PRIORITY**

This application claims the benefit of U.S. Provisional Application Serial No. 60/443,612 filed on January 30, 2003.

**III. RESTRICTION**

The Markush group set forth in the claims includes both independent and distinct inventions, and patentable distinct compounds or species within each invention. However, the instant application discloses and claims a plurality of patentable distinct inventions far too numerous to list individually. Moreover, each of these inventions contain a plurality of patentable distinct compounds, also far too numerous to list individually. Restriction to one of the following Inventions is required pursuant to 35 U.S.C. § 121, wherein an Invention is a set of patentable distinct inventions of a broad statutory category.

- I. Claims 1-53, drawn to active ester compounds, classified in various subclasses of various classes such as class 424, subclasses 1.37 and 1.81, class 544, subclasses 64, 112 and 141, class 546, subclasses 2, 208; class 548, subclass 402, and 520, for example.
- II. Claim 54-70, drawn to a kit, classified in class 435, subclass 810.

Markush Claims

A provisional election of a species is required because the Markush-type claims of the instant application include distinct independent inventions. Restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. See In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); See also Ex Parte Hozumi, 3 USPQ2d 1059 (BPAI 1984). Absent evidence that subject matter of the Markush-type claim lacks unity of invention, the Office may not merely “refuse to examine that which applicants regard as their invention.” See M.P.E.P. § 803.02; In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Additionally, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. § 103. **Therefore, in addition to an election of one of the abovementioned Inventions, restriction is further required under 35 U.S.C. § 121.**

If Invention I is elected, election of a single species is further required, including an exact definition of each substitution on the base molecule, Formula (I), wherein a single member at each substituent group is selected. For example, in the instant application, Claim 1 is a generic claim drawn to a 5-7 membered heterocyclic ring, for example. Applicant must select a single species and in the case where the heterocyclic ring has substituents the substituents and variable positions for the substituents must also be defined. This process is repeated for each variable so that a single compound is identified.

In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound. The

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elected compounds should be similar that they will encompass the same inventive concept and reduction to practice. The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound and the entire scope of the invention encompassing the elected compound as defined by common classification.

A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compound are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

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must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R.

1.17(i).

Applicants can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds, which are so similar, within the same inventive concept and reduction to practice. Markush claims require sufficient support in the disclosure for each member of the Markush group. See MPEP § 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the core structure as the selected species must be consistent with the written description.

*Rationale Establishing Patentable Distinctiveness Within Each Group*

Invention I and II are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes or operation, different functions or different effects. See MPEP §§ 806.04, 808.01. In the instant case, the kit and the compounds have varying modes of operation. The inventions are distinct, each from the other because they are drawn to different statutory subject matter and are classified differently. As such a search for Invention I would not encompass art of Invention II.

In conclusion, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Additionally, because of the plethora of classes and subclasses in each of the Inventions, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Lack of restriction would impose a serious burden on the Examiner. Thus, based on the abovementioned rationale, the restriction as set forth in the instant application is proper.

In sum, each Group listed above has a diverse chemical structure, different chemical properties, different modes of action, and different effects and reactive conditions and is therefore recognized in the art as being distinct from one another. MPEP §§ 806.04, 808.01. Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The rebuttable presumption, that similar chemical structures behave similarly, may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

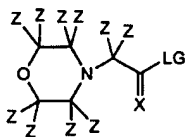
Telephone Inquiry

During a telephone conversation with Brian Gildea, Esquire on September 8, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-53, directed to compounds. Mr. Gildea also elected compound I in Figure IA as a provisional species of the genus. Claims 54-70 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicant is reminded that he/she is required to affirm this election when responding to this Office Action.

#### IV. ELECTION

##### Scope of the Elected Subject Matter Based on Compound I of FIG 1A

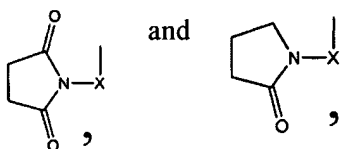
Applicant's telephonic election with traverse of the compound I in Figure 1A, in response to the requirement for restriction is acknowledged. Therefore, the elected invention for search and examination are compounds drawn to a 6 membered N substituted morpholine acetic acid ester of the formula



"Z" is defined in Claim 15;

"X" is oxygen; and

"LG" is



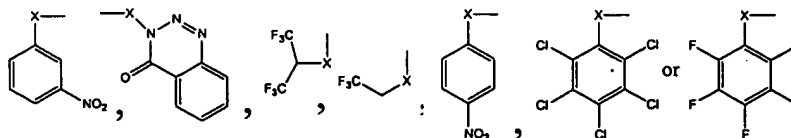
##### Scope of Withdrawn Subject Matter Not Drawn to Compound I of FIG 1A

The remaining subject matter of claims 1-53 that is not drawn to the abovementioned scope of invention stands withdrawn under 37 CFR § 1.142(b) as being for non-elected subject matter. The compounds are not within the elected invention, which are independent and distinct from the elected invention and do not have utility with the elected compound and are therefore withdrawn by way of restriction.

Compound of Claims 1-53 are withdrawn by way of restriction are the compounds drawn to *any* other 5, 6, or 7 membered heterocyclic ring comprising a nitrogen atom that is N-alkylated with an acetic acid moiety not drawn to the abovementioned scope of the elected invention wherein:

"X" is sulfur;

"LG" is





The abovementioned compounds are withdrawn from consideration as being non-elected subject matter. The invention as claimed in Claim 1, for example, is broad in scope and would encompass a multitude of compounds. The withdrawn compounds contain distinct substitutions such as triazoles, pyridine, pyrazine, piperazine, piperidine, or diazepane, etc., which differ significantly in structure and function. This structural and elemental variety of substitutions is exemplified by their classifications in the U.S. classification system. For example: diazepanes are classified in class 540, while pyrazines are classified in 544 and pyridines in class 546 and triazoles in 548. Therefore, the compounds are withdrawn as being non-elected subject matter that differs materially in structure and composition.

**V. EXTENDED PRIOR ART SEARCH PURSUANT TO MPEP 803.02**

If upon examination of the elected species, no prior art is found that would anticipate or render obvious the instant invention based on the elected species, the search of the Markush-type claim will be extended. See M.P.E.P. § 803.02 (2001). If prior art is then found that anticipates or renders obvious the non-elected species, the Markush-type claim will be rejected. It should be noted that the prior art search will not be extended unnecessarily to cover all non-elected species. Should Applicant overcome the rejection by amending the claim, the amended claim will be reexamined. Id. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. Id. In the event prior art is found during reexamination that renders obvious or anticipates the amended Markush-type claim, the claim will be rejected and the action made final. Id.

As indicated above, Examiner searched the compound based on the elected species, Compound I of Fig. 1A, in response to the restriction requirement. However, there was no prior art of record that anticipated or rendered obvious the elected species and therefore the scope of the subject matter was **extended or broaden** in pursuant to M.P.E.P. § 803.02.

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The prior art search was extended to include some of the non-elected species wherein the variable are defined as follows:

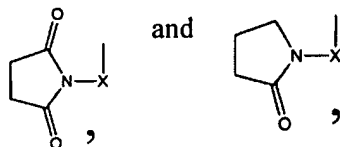
6 membered N substituted heterocyclic acetic acid ester of the formulae:



"Z" is defined in Claim 1;

"X" is oxygen or sulfur; and

"LG" is



The remaining variables are defined above.

## VI. REJECTIONS

### *Provisional Obviousness-Type Double Patenting*

Claims 1-14, 41-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19, 21-24 of copending Application No. 10/751,354. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). See also M.P.E.P. § 804 (2001).

Obvious-type nonstatutory double patenting rejection is “analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. §103” with the distinction that the double patent rejection is not considered prior art. Id. See also In re Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Thus, the analysis employed in an obviousness-type double patent rejection is consistent with a §103(a) analysis set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966).

Claims 1-6, 8-14, and 41-53<sup>1</sup> are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19, 21-24 of copending Application No. 10/751,354. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant Claim 1 recites and broadly claims based on the *elected subject matter*, an active ester compound that is a 6 membered saturated monocyclic heterocycle selected from the group consisting of 1,4-morpholine, 1,4-piperazine, and piperidine wherein the nitrogen atom is N-alkylated with an acetic acid moiety to which the alcohol moiety of the active ester is linked through the carbonyl carbon of the N-alkyl acetic acid moiety, wherein the compound is isotopically enriched with one or more heavy atom isotopes.

Instant claims 2-6 and 8-14 depend from claim 1 and add the following limitations: the compound of Claim 1 wherein:

- the compound is isotopically enriched with three or more heavy atom isotopes;
- the heterocyclic ring is substituted with one or more substituents;
- one or more substituents are alkyl, alkoxy or aryl;
- one or more substituents are protected or unprotected or unprotected amine groups, hydroxyl or thiol groups;

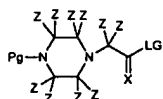
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<sup>1</sup> Claims 41-53 are also rejection for obvious double patenting because protecting group “PG” may encompass some or all of the “Y” groups of the copending application. *See* Examiner’s §112 rejection below.

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- heterocyclic ring is aliphatic;
- the heterocyclic ring comprises one or more additional nitrogen, oxygen or sulfur atoms;
- the active ester is an N-hydroxysuccinimide ester;
- the compound is a salt (mono-TFA, mono-HCL, bis-TFA or bis-HCL); and
- each incorporated heavy atom isotope is present in at least 80%, 93% or 96% isotopic purity.

Instant Claim 41 recites N-substituted piperazine acetic acid ester of the formula



Wherein PG is a protecting group. dependent claims 42-53 add the following

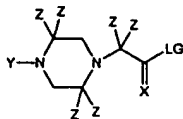
limitations: the compound of Claim 41 wherein:

- the compound is isotopically enriched with three or more heavy atom isotopes;
- Z is hydrogen, deuterium, fluorine, chlorine, bromine, iodine, methyl or methoxy;
- X is  $^{16}\text{O}$  or  $^{18}\text{O}$ ;
- N is  $^{14}\text{N}$  or  $^{15}\text{N}$ ;
- LG is an N-hydroxysuccinimide;
- the compound is a salt (mono-TFA, mono-HCL, bis-TFA or bis-HCL); and
- each incorporated heavy atom isotope is present in at least 80%, 93% or 96% isotopic purity.

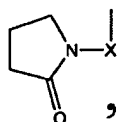
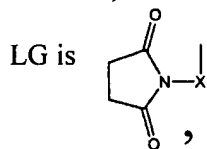
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Determining the Scope and Contents of the Co-pending Application

Conflicting claims 1-4, 6-19, 21-24 of copending Application No. 10/751,354 recite an N-substituted piperazine acetic acid active ester compound of the formula:



Or a salt thereof, wherein:



X is oxygen or sulfur;

Y is a straight or branched C1-C6 alkyl or a straight or branched C1-C6 alkyl ether group comprising hydrogen, deuterium or fluorine atoms;

Z is identical to the definition in Instant claim 1; and

the N-substituted piperazine acetic acid active ester comprises one or more heavy atom isotopes.

(See 10/751,354, p. 39, ll. 5-27).

Claims 2-4, and 6-12 and 21 of the copending application depend from claim 1 and add the following limitations: the compound of claim 1 wherein:

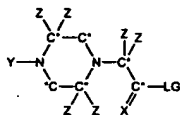
- the N-substituted piperazine acetic acid active ester is isotopically enriched with one or more heavy atom isotopes;
- the N-substituted piperazine acetic acid active ester is isotopically enriched with three or more heavy atom isotopes;

- LG is and and where X is O or S;

- LG is N-hydroxysuccinimide;
- Z is independently hydrogen, deuterium, fluorine, chlorine, bromine or iodine;

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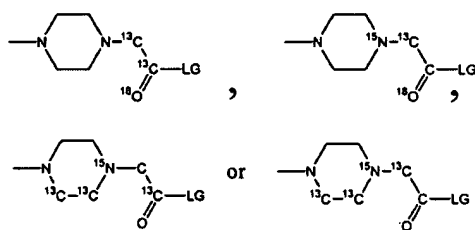
- Y is methyl, ethyl, n-propyl, isopropyl, n-butyl, isobutyl, sec-butyl or tert-butyl;
- X is  $^{16}\text{O}$  or  $^{18}\text{O}$ ;
- of formula



- the compound is a salt (mono-TFA, mono-HCL, bis-TFA or bis-HCL); and
- each incorporated heavy atom isotope is present in at least 80%, 93% or 96% isotopic purity;
- the N-substituted piperazine acetic acid active ester is a mono-TFA, mono-HCL, bis-HCL or bis-TFA salt

Claim 2 of the copending application recites the compound of claim 1 wherein the N-substituted piperazine acetic acid active ester is isotopically enriched with one or more heavy atom isotopes.

Claims 13, 22-24 of the copending application depend from claim 2 and recite the compound of the formula:

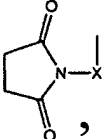
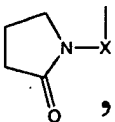


wherein LG is the leaving group of an active ester and wherein each incorporated heavy atom isotope is present in at least 80%, 93% or 96% isotopic purity.

Claims 14-19 of the copending application depend from claim 13 and add the following limitations: the compound of claim 13 wherein:

- the compound is mono-TFA, mono-HCL, bis-TFA or bis-HCL salt; and

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- each incorporated heavy atom isotope is present in at least 80%, 93% or 96% isotopic purity;
- wherein LG is N-hydroxysuccinimide
- LG is  and ,

Ascertaining the Differences Between the Copending Application and the Instant Claims

The difference between the instant application and the copending application is that the instant application recites a generic claim that encompasses the subspecies described in copending application 10/751,354. Specifically, the instant claims are drawn to 1,4-morpholines, 1,4-piperazines, and piperidines wherein the nitrogen atom is N-alkylated. The copending application is drawn to the 1,4-piperazine subgenus.

Resolving the Level of Ordinary Skill in the Pertinent Art

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the compounds of the instant application as the inventions are drawn to the same invention as mentioned and described above.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application that matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The variable “PG” in claim 41 and 49 is not defined in the Specification sufficiently to ascertain the structure of the protection group. Therefore, Claims 41-53 are rejected because they lack adequate support in the Specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For the reasons set forth above under 35 U.S.C. 112, 1<sup>st</sup> paragraph, Claims 41-53 are indefinite.

Claim 1, 15, 23, 28, 36, 41, and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claims 15, 23, 28, 36, 41, and 49 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

To overcome rejected Claim 1, the Applicant should define “heterocyclic ring” and “active ester” commensurate with the original specification and in light of the scope of the elected subject matter (e.g. 1,4-piperazine, 1,4-morpholine, N-hydroxysuccinimidyl, N-hydroxysulfosuccinimidyl ester, etc.).



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Applicant can also overcome the rejection by amending the claims to include the structures of the active ester compound and changing “comprising” to “consisting of.”

To overcome rejected Claims 15, 23, 28, 36, 41, and 49, Applicant should define “leaving group” and “amine protecting group” commensurate with the original specification and in light of the scope of the elected subject matter.

## **VII. OBJECTIONS**

### ***Claim Objection-Non Elected Subject Matter***

Claims 1-17, 19-30, 32-43, 45-53 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should rewrite instant Claims in independent form including all of the limitations of the base claim and any intervening claims and if rewritten directed solely to the elected subject matter indicated as being examinable.

### ***Dependent Claim Objections***

Dependent Claims 2-14 and 42-53 are also objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.

Claims 16-27, and 29-40 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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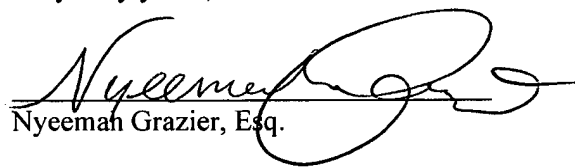
**VIII. CONCLUSION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

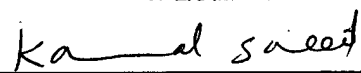
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,

  
Nyeemah Grazier, Esq.

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